World Journal of Gastroenterology

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DOI: 10.3748/wjg.v20.i45.16913

World J Gastroenterol 2014 December 7; 20(45): 16913-16924
ISSN 1007-9327 (print) ISSN 2219-2840 (online)

TOPIC HIGHLIGHT

WJG 20th Anniversary Special Issues (18): Pancreatitis

Balloon dilation itself may not be a major determinant of post-endoscopic retrograde cholangiopancreatography pancreatitis

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Received: February 27, 2014 Revised: August 2, 2014
Accepted: September 12, 2014
Published online: December 7, 2014

Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is the essential first modality for common bile duct (CBD) stone therapy. The conventional endoscopic treatment for CBD stones is stone removal after endoscopic sphincterotomy (EST). Stone removal after papillary stretching using balloon dilation instead of the conventional method has been widely adopted. There are many reports regarding endoscopic papillary balloon dilation (EPBD) utilizing a small balloon (< 10 mm) instead of EST for the removal of small CBD stones. In contrast, two cases of mortality due to post-ERCP pancreatitis (PEP) were reported after an EPBD clinical trial in the Western world, and the psychological barrier caused by these incidences hinders the use of this technique in Western countries. Endoscopic papillar large balloon dilation (EPLBD), which is used to treat large CBD stones, was not widely adopted when first introduced due to concerns about perforation and severe pancreatitis from the use of a large balloon (12-20 mm). However, as experience with this procedure accumulates, the occurrence of PEP with EPLBD is confirmed to be much lower than with EPBD. This report reviews whether EPBD and EPLBD, two procedures that use balloon dilation but differ in terms of indications and concept, contribute to the occurrence of PEP.

Key words: Post-endoscopic retrograde cholangiopancreatography pancreatitis; Endoscopic papillary balloon dilation; Endoscopic papillary large balloon dilation; Common bile duct stone

Core tip: Endoscopic papillary balloon dilation (EPBD) and endoscopic papillary large balloon dilation (EPLBD) have been performed for removal of common bile duct stones. Although the rates of post-endoscopic retrograde cholangiopanc- reatography pancreatitis (PEP) after EPBD and EPLBD varied in many studies, the safety and feasibility of balloon dilation have been proven as results have accumulated. However, the exact mechanism of PEP after balloon dilation is unclear. The main determinant of severe PEP may be edema or spasm caused by irritation of the pancreatic orifice while performing difficult selective cannulation and struggling to remove the stone rather than balloon compression of the pancreatic flow.

Jang SI, Yun GW, Lee DK. Balloon dilation itself may not be a major determinant of post-endoscopic retrograde cholangiopancreatography pancreatitis. *World J Gastroenterol* 2014; 20(45): 16913-16924 Available from: URL: http://www.wjgnet.com/1007-9327/full/v20/i45/16913.htm DOI: http://dx.doi.org/10.3748/wjg.v20.i45.16913

INTRODUCTION

Post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis (PEP) is a complicating adverse event, for which doctors can do little to treat. Removing common bile duct (CBD) stones is the most frequently performed procedure carried out using ERCP. Conventional endoscopic biliary stone removal through endoscopic sphincterotomy (EST) has been replaced by the balloon dilation method.

PEP, the most common and potentially serious complication of ERCP-related procedures, occurs in 1%-9% of all procedures[1]. Many studies of the risk and predictive factors to prevent PEP have been conducted[1-16]. To discuss the risk factors for PEP, not only procedural and technical factors but also patient characteristics should be considered[1,15]. Patient-related factors for PEP include a history of post-ERCP pancreatitis[1,9,10,12,16,17], female sex[1,10,15], young age[3,4,6,12,15], suspected sphincter of Oddi dysfunction (SOD)[1,2,4,10,12,14], and absence of chronic pancreatitis[1]. Procedural-related factors include difficult cannulation[1,9,15-17], precut sphincterotomy[2,10,15,16], pancreatic deep wire pass[15], pancreatic sphincterotomy[1], pancreatic contrast injections[1-4,10,12,17,18], and biliary balloon sphincter dilation[1]. These reported risk factors vary among studies, and some contradict each other. Hence, the data for risk factors for PEP should be interpreted with caution. Such discrepancies may have arisen from heterogeneous patient populations or from differences in the level of endoscopic expertise, cannulation techniques, and definition of post-ERCP pancreatitis[12].

The PEP mechanism is not well defined, but it is commonly accepted to be multifactorial, involving mechanical, chemical, hydrostatic, enzymatic, microbial, and thermal factors[1,12]. A certain triggering event may prematurely activate proteolytic enzymes intracellularly within acinar cells, which may cause cellular injury and autodigestion of pancreatic tissue[19,20]. Various PEP mechanisms have been suggested. PEP may occur from incidental injection of contrast medium into the pancreatic duct in cases where cannulation of the bile duct is difficult; in such cases, the type of contrast medium injected and the speed and pressure of injection leading to complete acinar filling of the pancreas can have an influence[8,21-23]. Hydrostatic injury caused by pancreatic duct overfilling may be a major trigger factor for pancreatic reactions[16]. Difficult cannulation may inflict trauma to the papilla and pancreatic sphincter, leading to pancreatic drainage disruption and causing PEP[12,24,25]. Pancreatitis after pancreatic sphincterotomy, and precutting have been discussed based on the possibility of incidental temporary obstruction of the pancreatic duct, caused by direct thermal damage to the duct by the cutting wire or by edema induced by thermal tissue injury[8,26]. PEP occurs more frequently in patients with SOD[1,2,10,14,24,27-29], which may cause a flow disturbance in pancreatic drainage due to pancreatic sphincter hypertension.

Balloon inflation is also a possible cause of PEP. The pancreatic orifice is compressed during ballooning, and pancreatic flow is transiently disrupted. However, it is unknown whether ballooning itself is a major determinant for the development of PEP due to endoscopic papillary balloon dilation (EPBD) and endoscopic papillary large balloon dilation (EPLBD). This report provides a systemic review of how the balloon itself affects PEP in balloon dilation during EPBD and EPLBD.

ENDOSCOPIC PAPILLARY BALLOON DILATION AND ENDOSCOPIC PAPILLARY LARGE BALLOON DILATION

Definition and concepts

The ampullary orifice and distal CBD are dilated temporarily by balloon dilation during EPBD and EPLBD procedures. However, EPBD and EPLBD are not the same procedure in either concept or indications. EPBD is performed in patients with a non- or minimally dilated CBD[30]. In contrast, EPLBD should be performed in patients with dilated CBD and ampulla due to a large long-standing stone. Ballooning of the CBD and ampullary orifice stretches the tissue transiently to form a tubular shape to facilitate stone removal. In this process, successful dilation depends on the elasticity, the degree of dilation of the CBD tissue, and the absence of stricture. Moreover, the ease of selective bile duct cannulation and stone removal through the widened ampullary orifice might be associated with the occurrence of PEP.

EPBD has been performed to dilate the biliary sphincter without prior EST by using a small-diameter dilating balloon ($\leqslant$ 10 mm). EPBD can avoid the short-term complications of bleeding and perforation, preserve the function of the biliary sphincter, and reduce long-term sequelae of EST. Additionally, EPLBD has been used to remove large CBD stones after dilating the biliary sphincter with EST using a large-diameter dilation ($\geqslant$ 12 mm). EPLBD can reduce the use of mechanical lithotripsy (MLT), thereby avoiding complications related to the use of full EST for the removal of large or difficult CBD stones. The majority of EPLBDs involve limited EST (minimal or mid-EST rather than full EST) followed by large balloon inflation. If EST is performed toward the CBD, tearing advances in the same direction[31]. This combined approach does not require full EST and can enlarge the biliary orifice to a greater extent than a standard full EST[30].

Indications

EPBD is a possible alternative to EST in patients with impaired hemostasis[11]. To maximize the effect of EPBD while minimizing complications, a technique with proper indication and in the proper manner is necessary[32]. Recommended indications for balloon dilation include coagulopathy, periampullary diverticulum, Billroth II gastrojejunostomy, and prior EST status[32]. Another study suggested that the ideal patients are those with a limited number of CBD stones ($\leqslant$ 3), CBD stones of a maximum diameter $\leqslant$ 10 mm, and minimally dilated bile

duct[33]. In addition, in cases with difficult cannulation, impractical cannulation should be avoided. The use of EPBD for removing CBD stones > 10 mm may necessitate a laborious and papilla-traumatic procedure, such as MLT, and may increase the risk of pancreatitis[34]. EPBD for a large CBD stone requires multiple sessions and is time-consuming because the biliary orifice is not dilated sufficiently[35]. Therefore, relatively large stones with a non-dilated CBD are not good candidates for EPBD. Further large-scale studies with a longer follow-up are imperative to identify more distinct indications and the optimum method.

Strict indications are needed for EPLBD to avoid serious adverse events. The patients suitable for this method are those who already have a dilated CBD due to a large stone[36]. The tissue of ampulla and distal CBD in these patients are ready to be dilated and further gradual stretching of the tissue will not cause stress or sudden tearing of the ampullary roof. However, patients with the CBD of less than the balloon size or strictures of the distal CBD should be excluded because of the possibility of perforation. The velocity and duration of balloon inflation vary across studies, ranging from a few seconds to minutes. Although guidelines pertaining to the optimal velocity of balloon inflation have yet to be established, the following guidelines for safe EPLBD were proposed based on the current knowledge[36,37]: (1) selection of suitable candidates; *i.e.*, EPLBD should be reserved for patients with a dilated CBD, but avoided in patients with distal CBD strictures; (2) avoidance of full-EST immediately before large balloon dilation to prevent perforation and bleeding; (3) gradual inflation of the dilating balloon to recognize a narrowed distal CBD indicated by lack of disappearance of the balloon waist; (4) discontinuation of inflation when resistance is encountered in the presence of a persistent balloon waist; (5) not inflating the dilation balloon beyond the maximal size of the upstream dilated CBD; and (6) conversion to alternative stone removal or drainage methods when difficulty in removal of a stone is encountered. When a tapered, distal CBD or occult stricture is identified, the operator should pay particular attention to avoiding fatal adverse events caused by large perforations occurring during balloon inflation.

BALLOONING AND PEP

Acute pancreatitis after endoscopic papillary balloon dilation

EPBD, suggested by Staritz *et al*[38], is an alternative method to EST for removal of CBD stones. EPBD was adopted to reduce the risk of bleeding[39-42] and preserve the function of the sphincter of Oddi[40,43-47]. Some studies have reported that there was no difference in efficacy and safety between EST and EPBD[46,48], whereas others claimed that the incidence of pancreatitis was higher among patients who received EPBD compared with those who received EST[33,49,50]. The results of randomized control studies comparing EPBD and EST are inconsistent, particularly in terms of the incidence and severity of PEP[46,48-50]. Severe morbidity in the EPBD group compared with the EST group caused early termination of one study[51], and some clinicians assert that EPBD should not be performed based on the pancreatitis-induced mortality that occurred during some studies[50,52]. In particular, another randomized, controlled multicenter trial was also terminated early during the first interim analysis, because two patients died from severe pancreatitis as a complication of EPBD[50]. Thus, the investigation of risk factors for EPBD-related pancreatitis remains controversial.

In studies from Holland[46] and the United Kingdom[48], the incidence rates of pancreatitis with EPBD appeared to be similar to those with EST. In a Japanese study, the pancreatitis rate was slightly higher with EPBD than with EST[49]. In contrast, an American study by Disario *et al*[50] reported that the post-EPBD pancreatitis rate was higher than that of EST, and mortality was due to pancreatitis. Although EPBD is used less frequently in Western countries due to these complications, it has been continuously adopted in some Japanese groups. There is no clear explanation for this discrepancy, but it is presumed that differences in patient populations and methods of balloon dilation may play a role[42]. In addition, the US study may have included patients with SOD[42]. Thus, pancreatitis-associated EPBD is a very controversial and serious topic[53,54].

The incidence of acute pancreatitis after EPBD ranges from 5%-20%, although most figures fall in the range of 5%-7%[43,46,51]. The frequency and severity of PEP following EPBD are summarized in Table 1. The precise mechanism underlying post-EPBD pancreatitis is not well defined, and appears to be multifactorial. Contrast medium injection into the pancreatic duct[11] and a history of prior pancreatitis[54] are suggested to be risk factors for post-EPBD pancreatitis. Younger age is a risk factor for post-ERCP pancreatitis[3,4,6,12,15], but not for post-EPBD pancreatitis[11,54]. However, in real practice, most cases of severe pancreatitis involve relatively young patients with unatrophied pancreatic tissue.

The mechanism of pancreatitis induced by superfluous injection of contrast medium is regarded as the same as that with EST[11]. Some research suggests that papillary edema or spasm caused by balloon dilation can result in pancreatitis by obstructing pancreatic outflow[11,42]. Balloon compression of the papilla or the pancreatic duct orifice may provoke peripapillary edema and/or spasm of the sphincter of Oddi[51,53]. However, peripapillary trauma by cannulation can more definitely and frequently provoke spasm of the sphincter of Oddi and/or hemorrhagic edematous change[55], and it is a potential risk factor for asymptomatic hyperamylasemia after EPBD[54]. In addition, the biliary orifice may not fully dilate during stone removal with EPBD[56,57]. In this situation, stone removal can be more technically challenging and time-consuming[46,50,58], and subsequent papillary injury or edema during stone extraction can cause pancreatitis[35].

Table 1 Frequency and severity of pancreatitis and complications after endoscopic papillary balloon dilation

Ref.	Study design	Study's location	Comparison groups (*n*)	Pancreatitis *n* (%)	Pancreatitis severity (*n*)			Other complications (*n*)			Overall AEs-related death (*n*)
					Mild/ moderate	Severe	Death	Bleeding	Perforation	Cholangitis	
Minami *et al*[85], (1995)	RCT	Japan	EPBD (*n* = 20)	2 (10)	2	0	0	0	0	0	0
			EST (*n* = 20)	2 (10)	2	0	0	0	0	0	0
Mathuna *et al*[86], (1995)	R	Ireland	EPBD (*n* = 100)	5 (4.8)	5	0	0	0	0	0	0
Bergman *et al*[46], (1997)	RCT	The Netherlands	EPBD (*n* = 101)	7 (6.9)	5	2	0	0	2	0	0
			EST (*n* = 101)	7 (6.9)	6	1	0	4	1	0	1
Yasuda *et al*[87], (1998)	P	Japan	EPBD (*n* = 92)	8 (8.7)	8	0	0	0	0	0	0
Ueno *et al*[55], (1999)	R	Japan	EPBD (*n* = 109)	21 (19.8)	21	0	0	NA	NA	NA	0
Ochi *et al*[88], (1999)	RCT	Japan	EPBD (*n* = 55)	0	0	0	0	0	0	0	0
			EST (*n* = 55)	2 (3.6)	2	0	0	0	1	0	0
Arnold *et al*[51], (2001)	RCT	Germany	EPBD (*n* = 30)	6 (20.0)	4	2	0	0	0	3	0
			EST (*n* = 30)	3 (10.0)	3	0	0	2	0	0	0
Bergman *et al*[53], (2001)	RCT	The Netherlands	EPBD (*n* = 93)	7 (7.5)	5	2	0	0	2	0	1
			EST (*n* = 87)	7 (8.0)	6	1	0	2	0	0	0
Yasuda *et al*[43], (2001)	RCT	Japan	EPBD (*n* = 35)	2 (5.7)	2	0	0	0	0	0	0
			EST (*n* = 35)	2 (5.7)	2	0	0	1	0	0	0
Natsui *et al*[89], (2002)	RCT	Japan	EPBD (*n* = 70)	4 (5.7)	4	0	0	0	0	2	
			EST (*n* = 70)	3 (4.3)	3	0	0	2	0	3	
Fujita *et al*[49], (2003)	RCT	Japan	EPBD (*n* = 138)	15 (10.9)	15	0	0	0	0	2	0
			EST (*n* = 144)	4 (2.7)	4	0	0	2	0	6	0
Vlavianos *et al*[48], (2003)	RCT	United Kindom	EPBD (*n* = 103)	5 (4.9)	4	1	0	0	0	2	0
			EST (*n* = 99)	1 (1.0)	1	0	0	0	0	1	1
Sugiyama *et al*[54], (2003)	R	Japan	EPBD (*n* = 118)	7 (6.0)	7	0	0	0	0	0	0
Lin *et al*[90], (2004)	RCT	Taiwan	EPBD (*n* = 51)	0	0	0	0	1	0	0	0
			EST (*n* = 53)	0	0	0	0	14	0	0	0
Disario *et al*[50], (2004)	RCT	United States	EPBD (*n* = 117)	18 (15.4)	12	6	2	11	0	1	2
			EST (*n* = 120)	1 (0.8)	1	0	0	32	1	1	0
Tanake *et al*[91], (2004)	RCT	Japan	EPBD (*n* = 16)	3 (18.8)	1	2	0	0	0	0	0
			EST (*n* = 16)	3 (18.8)	2	1	0	0	0	2	0
Toda *et al*[92], (2005)	RCT	Japan	EPBD (*n* = 94)	7 (6.4)	7	0	0	0	0	4	0
			EST (*n* = 102)	3 (3)	3	0	0	2	2	4	0
Tsujino *et al*[11], (2005)	R	Japan	EPBD (*n* = 304)	15 (5.0)	15	0	0	0	1	6	0
Nakagawa *et al*[93], (2006)	R	Japan	EPBD (*n* = 201)	2 (1.0)	0	2	0	0	0	3	0
Tsujino *et al*[42], (2007)	P	Japan	EPBD (*n* = 1000)	48 (4.8)	47	1	0	2	2	27	2
Ito *et al*[35], (2008)	R	Japan	EPBD (*n* = 406)	19 (5.7)	19	0	0	0	1	4	0
Liao *et al*[94], (2008)	RCT	Taiwan	EPBD (*n* = 35)	2 (5.7)	2	0	0	0	0	1	0
			EST (*n* = 25)	3 (12)	3	0	0	2	0	2	0
Natsui *et al*[95], (2011)	RCT	Japan	EPBD (*n* = 41)	2 (4.8)	2	0	0	0	0	1	0
			EST (*n* = 42)	1 (2.3)	1	0	0	0	0	1	0
Kuo *et al*[96], (2012)	R	Taiwan	EPBD (*n* = 273)	30 (10.1)	22	8	0	1	1	9	1
Seo *et al*[97], (2014)	RCT	South Korea	EPBD (*n* = 62)	5 (8.1)	5	0	0	0	0	0	0
			EST (*n* = 70)	5 (7.1)	5	0	0	2	1	0	0

EST: Endoscopic sphincterotomy; AEs: Adverse events; EPBD: Endoscopic papillary balloon dilation; R: Retrospective; P: Prospective; RCT: Randomized controlled trial; NA: Not available.

In particular, stone removal by EPBD becomes more difficult when the stone is large and the use of MLT is more frequent[33,50]. In such cases, the biliary orifice is more likely to be damaged, and the risk of pancreatitis can be greater.

Acute pancreatitis after endoscopic papillary large balloon dilation with EST

EPLBD with limited EST is gradually being recognized as an important modality for the removal of large CBD stones[36,59-67]. Pancreatitis occurs in 2.4% (0%-13.2%) of

patients; almost all cases have been of mild to moderate severity (98.4%)[37,68,69]. The frequency and severity of PEP after EPLBD with EST are summarized in Table 2.

Standard procedural guidelines have not been established; yet, most procedures involve limited EST followed by large balloon inflation. If EST is performed toward the CBD, the direction of tearing advances toward the CBD, and less pressure is applied on the pancreatic duct[31]. It has been suggested that the radial force generated by the dilating balloon is exerted toward the CBD and moves away from the pancreatic duct, which lessens the likelihood of pancreatitis by reducing periampullary injury[31,36,37,62,70]. Moreover, and in contrast to EPBD, EPLBD dilates the ampullary orifice sufficiently to allow for straightforward removal of a large CBD stone, using a Dormia basket or retrieval balloon, and so that it is wide enough to reduce the need for MLT[71]. Additionally, because of the patulous papillary orifice caused by a large stone, endoscopists feel comfortable with selective cannulation of the bile duct in most patients. These are all reasons for decreased occurrence of pancreatitis by reduced ampulla injury, which can cause periempullary trauma or edema[36].

Surprisingly, according to a multicenter retrospective study[37], there was no severe PEP after EPLBD among 946 patients. This provides strong evidence that ballooning itself is not a major determinant of PEP in EPLBD. Moreover, according to a systemic review of EPLBD, even though the inclusion criteria and procedure type were heterogeneous[69], PEP following EPLBD was not problematic. The duration of ballooning in EPLBD is usually 30-60 s in real practice. However, the timing of balloon inflation is not related to PEP[30,69], so prolonged balloon inflation does not increase PEP in EPLBD.

Acute pancreatitis after EPLBD without EST

EPLBD without EST is preferred in patients with bleeding tendencies, altered anatomy, and, in some cases, periampullary diverticulum[34]. If EST is not performed prior to balloon application, theoretically, the PEP rate may increase because pancreatic outflow could be more completely obstructed by the balloon. In addition, the balloon could press the pancreatic orifice from a more acute angle than when the papillary roof incision is made, because the biliary and pancreatic orifices are not separated. However, according to a retrospective analysis[30] and systematic review[69], the PEP rate is not high and does not differ between EPLBD with and without EST. Moreover, the incidence of PEP did not change with ballooning time[68]. Therefore, ballooning during EPLBD is not a major factor for PEP, regardless of whether EST is performed.

Some recent studies have reported that EPLBD without EST is safe and effective in patients with large CBD stones[34,72,73]. Pancreatitis and bleeding occurred at a rate of 0.8%-6.5%, and all cases were of mild to moderate severity. The frequency and severity of PEP after EPLBD without EST are summarized in Table 3. This is supported by a large-scale study reporting less frequent pancreatitis resulting from a larger balloon[37]. In other words, the extent of biliary orifice dilation is relevant to the incidence of pancreatitis, rather than the size of the balloon, EST performance, or balloon dilation time[65,68,73].

DISCUSSION

Although EPBD involves a high incidence of pancreatitis, the reports are inconsistent, and it remains controversial. In studies with high rates of pancreatitis, a discrepancy in patient selection should have been made before suggesting balloon dilation as the primary risk factor for pancreatitis. The reason for the high incidence of pancreatitis in EPBD is that enables removal of only small-to-medium sized stones, and patients with such a stone size tend to possess the known risk factors for pancreatitis: young age, non-dilated CBD, normal pancreas parenchyma, obesity, and SOD dysfunction. In other words, careful patient selection can lessen the risk of post-ERCP pancreatitis. EPBD for larger CBD stones, rather than a non-dilated CBD, requires multiple sessions and is more time consuming for stone removal than EST, because EPBD cannot dilate the biliary orifice sufficiently[35]. Baron *et al*[33] recommended extreme caution when performing EBPD in patients with severe acute cholangitis, a history of previous or ongoing acute pancreatitis, age $\leqslant$ 50 years, and difficult biliary cannulation. To prevent post-ERCP pancreatitis, pancreatic duct stent insertion is also recommended when EPBD is performed in young patients[33].

The frequency or severity of PEP after EPBD did not vary with ballooning time. This implies that balloon compression of the pancreatic orifice for < 1 or 2 min without stimulated pancreatic secretion does not cause significant pancreatitis. In one randomized prospective study[74], 5-min EPBD reduced the risk of pancreatitis compared with conventional 1-min EPBD. Rather than ballooning itself, we believe that pancreatic edema or spasm caused by papillary irritation due to difficult selective cannulation and forcible stone extraction might be the major determinant of PEP after EPBD.

During the early period of EPLBD, PEP is the main concern, because the pancreatic orifice is compressed with a balloon larger than that used in EPBD. However, accumulated data inform clinicians that the larger balloon does not result in PEP, although in practice, one case of severe pancreatitis with mortality has been reported[75]. Although the major etiological factors of pancreatitis and its mechanism remain unclear, the mechanism of pancreatitis may differ between EPLBD and EPBD. EPLBD and EPBD are different procedures clinically. The major difference is that EPLBD cannot be applied to a non-dilated bile duct, which can be a risk factor for PEP[54]. If the orifice is sufficiently dilated by EPLBD, papillary edema or spasm is less likely to occur due to use of a basket or retrieval balloon catheter, unlike EPBD, and the incidence of pancreatitis may decline due to the less frequent

Table 2 Frequency and severity of pancreatitis and complications after endoscopic papillary large balloon dilation with endoscopic sphincterotomy

Ref.	Study design	Study's location	Comparison groups (*n*)	Balloon diameter (mm)	Pancreatitis *n* (%)	Pancreatitis severity (*n*)			Other complications (*n*)			Overall AEs-related death (*n*)
						Mild/ moderate	Severe	death	Bleeding	Perforation	Cholangitis	
Ersoz *et al*[31], (2003)	R	Turkey	EPLBD (*n* = 58)	12-20	2 (3.4)	2	0	0	5	0	2	0
Maydeo *et al*[60], (2007)	P	India	EPLBD (*n* = 60)	12-20	0 (0)	0	0	0	5	0	0	0
Minami *et al*[62], (2007)	R	Japan	EPLBD (*n* = 88)	20	1 (1.1)	1	0	0	1	0	1	0
Heo *et al*[61], (2007)	RCT	South Korea	EPLBD (*n* = 100)	12-20	4 (4.0)	4	0	0	0	0	0	0
			EST (*n* = 100)	-	4 (4.0)	4	0	0	2	0	0	0
Lee *et al*[98], (2007)	R	South Korea	EPLBD (*n* = 55)	15-20	0 (0)	0	0	0	2	0	0	0
Kim *et al*[99], (2007)	R	South Korea	EPLBD (*n* = 35)	12-20	0 (0)	0	0	0	0	1	0	0
Lee *et al*[100], (2007)	R	South Korea	EPLBD (*n* = 41)	13-20	2 (4.8)	0	0	0	1	0	0	0
Misra *et al*[101], (2008)	R	India	EPLBD (*n* = 50)	15-20	4 (8.0)	4	0	0	3	0	0	0
Attasaranya *et al*[63], (2008)	R	United States	EPLBD (*n* = 103)	12-18	0 (0)	0	0	0	2	1	0	0
Espinel *et al*[102], (2008)	P	Spain	EPLBD (*n* = 93)	12-20	1 (1.1)	1	0	0	1	0	0	0
Itoi *et al*[103], (2009)	R	Japan	EPLBD (*n* = 53)	15-20	1 (1.9)	1	0	0	0	0	1	0
			EST (*n* = 48)	-	2 (4.1)	2	0	0	0	0	1	0
Kim *et al*[104], (2009)	RCT	South Korea	EPLBD (*n* = 27)	15-18	0 (0)	0	0	0	4	0	0	0
			EST (*n* = 28)	-	0 (0)	0	0	0	2	0	0	0
Itoi *et al*[105], (2010)	R	Japan	EPLBD (*n* = 18)	15-18	0 (0)	0	0	0	0	0	0	0
Kurita *et al*[106], (2010)	R	Japan	EPLBD (*n* = 24)	15-20	0 (0)	0	0	0	0	0	0	0
Ghazanfar *et al*[107], (2010)	P	Pakistan	EPLBD (*n* = 84)	15-18	3 (3.6)	3	0	0	3	0	0	1
Kim *et al*[108], (2010)	R	South Korea	EPLBD (*n* = 70)	12-18	1 (2.3)	1	0	0	0	0	0	0
Youn *et al*[65], (2011)	R	South Korea	EPLBD (*n* = 101)	15-20	2 (2.0)	2	0	0	2	1	0	0
Kim *et al*[109], (2011)	R	South Korea	EPLBD (*n* = 72)	12-20	5 (6.9)	5	0	0	0	0	1	0
			EST (*n* = 77)	-	9 (11.7)	9	0	0	0	1	0	0
Stefanidis *et al*[75], (2011)	RCT	Greece	EPLBD (*n* = 45)	15-20	1 (2.2)	1	0	0	1	0	0	0
			EST (*n* = 45)	-	1 (2.2)	1	0	0	1	1	6	0
Rebelo *et al*[67], (2012)	R	Portugal	EPLBD (*n* = 30)	12-18	1 (3.3)	1	0	0	0	0	0	0
Sakai *et al*[110], (2013)	R	Japan	EPLBD (*n* = 59)	12-20	0 (0)	0	0	0	1	1	0	0
Park *et al*[37], (2013)	R	South Korea, Japan	EPLBD (*n* = 946)	12-20	24 (25.3)	24	0	0	56	9	6	4
Poincloux *et al*[64], (2013)	R	France	EPLBD (*n* = 64)	15-20	2 (3.1)	2	0	0	5	0	0	0
Hwang *et al*[73], (2013)	R	South Korea	EPLBD (*n* = 69)	12-20	3 (4.3)	3	0	0	0	1	0	0
Paspatis *et al*[68], (2013)	RCT	Greece	60 s dilation[1] (*n* = 60)	15-20	2 (1.6)	2	0	0	4	1	3	0
			30 s dilation[1] (*n* = 64)	15-20	2 (1.6)	1	1	1	2	1	2	1
Rosa *et al*[66], (2013)	R	Portugal	EPLBD (*n* = 68)	12-18	9 (13.2)	9	0	0	0	0	1	0
			EST (*n* = 45)	-	2 (4.7)	2	0	0	0	0	1	0

Yang *et al*[111], (2013)	R	China	EPLBD (n = 171)	12-18	2 (1.2)	2	0	0	4	1	1	0
Yoon *et al*[112], (2013)	P	South Korea	EPLBD (n = 52)	12-20	0 (0)	0	0	0	0	0	0	0
Harada *et al*[113], (2013)	R	Japan	EPLBD (n = 30)	15-20	0 (0)	0	0	0	0	0	0	0

[1]Sixty and thirty seconds mean the duration of balloon dilation (s) in endoscopic papillary large balloon dilation (EPLBD). AEs: Adverse events; EST: Endoscopic sphincterotomy; R: Retrospective; P: Prospective; RCT: Randomized controlled trial.

Table 3 Frequency and severity of pancreatitis and complications after endoscopic papillary large balloon dilation without endoscopic sphincterotomy

Ref.	Years	Study design	Patients (n)	Pancreatitis n (%)	Pancreatitis severity (n)				Other complications (n)			Overall AEs-related death (n)
					Mild	Moderate	Severe	Death	Bleeding	Perforation	Cholangitis	
Jeong *et al*[34]	2009	R	38	1 (2.6)	1	0	0	0	0	0	0	0
Chan *et al*[72]	2011	R	247	2 (0.8)	2	0	0	0	0	0	1	0
Hwang *et al*[73]	2013	R	62	4 (6.4)	4	0	0	0	0	0	0	0

AEs: Adverse events; R: Retrospective.

use of MLT[34,72]. There is no significant difference in the frequency of the requirement for MLT between EPLBD and the conventional method. However, adequate fragmentation of the CBD stone by MLT after EPLBD can reduce the frequency of the requirement for MLT in EPLBD compared with the conventional method[69]. This could be one reason for the lower incidence of PEP in EPLBD. Patients who receive EPLBD are relatively older individuals in whom pancreatic exocrine function has declined, and pancreatitis is less likely[72]. Further, easy selective cannulation into the bile duct can reduce the incidence of pancreatitis. Additionally, contrary to our concern, EPLBD without a preceding papillary incision did not cause severe pancreatitis[34,72,73]. Therefore, ballooning itself may not be the culprit. And the cause of fatal pancreatitis during EPBD should be reconsidered.

The incidence of pancreatitis, using percutaneous papillary balloon dilation (PTPBD) for CBD stone removal, is extremely low (0%-1.4%)[76-82]. A retrospective study reported that pancreatitis occurred only in the EPBD group; in another study, comparing PTPBD with EPBD, the only significant predictor was the use of MLT[76]. The size of the balloon used in PTPBD varies (4-23 mm) among studies and can also vary within the same study, due to the presence of differently sized CBD stones (5-20 mm)[77-82]. In one study[76], patients with a CBD stone < 12 mm in diameter were enrolled homogenously, and the balloon dilation diameter was 8-10 mm, which was compatible with EPBD. The largest balloons used for papillary dilation were of diameters 22 mm[80] and 23 mm[82] in other studies; this balloon inflation size is compatible with EPLBD. Although the balloon dilation diameter was different in each study, no severe pancreatitis occurred. These studies confirmed that ballooning does not increase the incidence of PEP. Moreover, the rates of post-procedural pancreatitis and hyperamylasemia were significantly higher following retrograde dilation using EPBD, compared with antegrade dilation using PTPBD, during the removal of bile duct stones[76].

The reason for the lower rate of PEP with antegrade application of balloon inflation compared with a retrograde fashion is the lack of difficulty in selective cannulation and lower chance of difficult procedure for forcible removal unless the stone descends. Compared with EPBD, PTPBD inflicts less mechanical trauma to papilla during stone removal, and it is nearly equivalent to the effect of ballooning[83,84]. In addition, MLT application does not involve lithotripsy moving back and forth through the ampullary orifice, in which there is no chance of pancreatic orifice damage. Such a result demonstrates that ballooning may not be a risk factor for pancreatitis. Moreover, the rates of post-procedural pancreatitis and hyperamylasemia were significantly higher after retrograde dilation with EPBD than after antegrade dilation with PTPBD for the removal of bile duct stones. This reveals that pancreatitis can be induced by other factors, such as repeated cannulation or pancreatic duct injection, during retrograde dilation with EPBD.

CONCLUSION

Although the mechanism of PEP is unclear, the occurrence of pancreatitis is more associated with the catheter, basket, or MLT causing ampullary injury. Instead of balloon compression of the pancreatic flow, the main determinants of severe pancreatitis during endoscopic stone removal with balloon dilation may involve edema or spasm caused by irritation of the pancreatic orifice while performing difficult selective cannulation and struggling to remove the stone. Therefore, ballooning itself may not be the culprit for PEP in either EPBD or EPLBD.

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P- Reviewer: Fujii L, Kawakami H, Kawakubo K
S- Editor: Gou SX **L- Editor**: A **E- Editor**: Wang CH

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ISSN 1007-9327